User Manual

EN

Mistral-Air® Plus Forced Air Warming

TSCI

The Surgical Company International B.V.

mistral-air®
www.mistral-air.nl

User Manual

Mistral-Air® Plus Warming Unit

MA1100-EU (220-240V~,50/60Hz)
MA1100-US (110-120V~,60Hz)
MA1100-JP (100-110V~,50/60Hz)

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Foreword

Congratulations on your purchase of the Mistral-Air® Plus Forced Air Warming Unit.
This device was developed with and for users and was built in accordance to the latest safety standards.
We wish you every success in preventing and controlling hypothermia and are sure the Mistral-Air® Plus warming unit can help you to do so.
Please read this manual carefully before using the Mistral-Air® Plus warming unit.

If you identify any improvements and/or discover any other applications during the use of the Mistral-Air® products, please let us know.

The Surgical Company International B.V. (TSCI)

Disclaimer

All rights reserved. No part of this document may be reproduced or published, electronically, mechanically, in print, photographic print, on microfilm or by any other means whatsoever, without the explicit consent of TSCI.

The content of this document has been compiled with the greatest possible care and this information can be regarded as reliable. Nevertheless,
TSCI is not liable for any consequences arising from the use of the manual.

TSCI reserves the right to make alterations and improvements to the device. These cannot yet be described in the instructions. TSCI B.V. cannot be held liable for the final outcome of the patients' treatment.

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These instructions are intended for personnel authorised to work with and/or service the medical device mentioned in this manual.

1 Temperature Management

Hypothermia, an abnormal drop in body temperature, is a threat to human life. Hospital patients in particular run serious risks if their body temperature falls below 36 °C. The risk of hypothermia is particularly high at moments when they are vulnerable, such as pre-, per-, and post-surgical interventions. Factors that can contribute to hypothermia include the duration of the surgical intervention, the location of the wound, the amount of blood loss, the surface area of the wound, the environmental temperature and the anaesthetic technique.

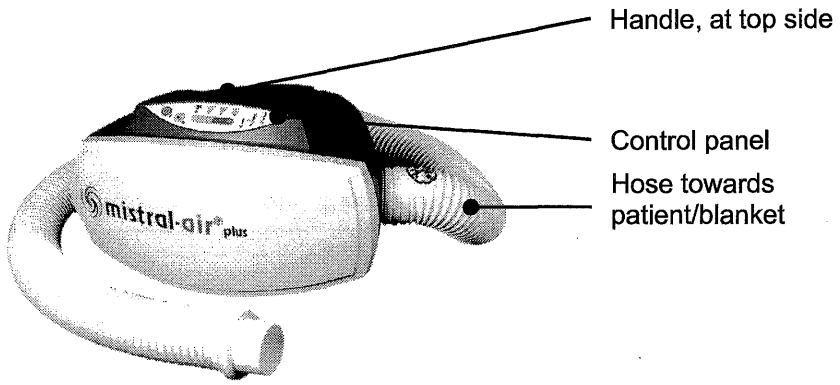
2 Forced Air Warming

Forced air warming is a widely used and clinically accepted intervention for the prevention of hypothermia and/or re-warming of the postoperative surgical patient. The principle of operation for forced air warming systems is an electrically powered unit consisting of a fan and heating element that propels warmed air via a flexible hose to a blanket draped over the patient.
Some configurations allow for the patient to be placed on top of the blanket or surrounded by a warming tube.
All of these forced air warming systems are intended to distribute warmed air to the patient in a manner that is safe and effective.

3 Description of Mistral-Air® Plus warming unit

The Mistral-Air® Plus warming unit is a system which is intended for use in preventing patients from getting hypothermic.
The Mistral-Air® Plus warming unit shall only be used with disposable Mistral-Air® blankets that are single patient use only.

3.1 The Appliance



The Mistral-Air® Plus warming unit can be controlled by using the control panel at the front top of the unit. The clamp to fix the Mistral-Air® Plus warming unit to a stand is positioned at the back of the unit.

Article number: - MA1100-EU (220-240V~,50/60Hz)
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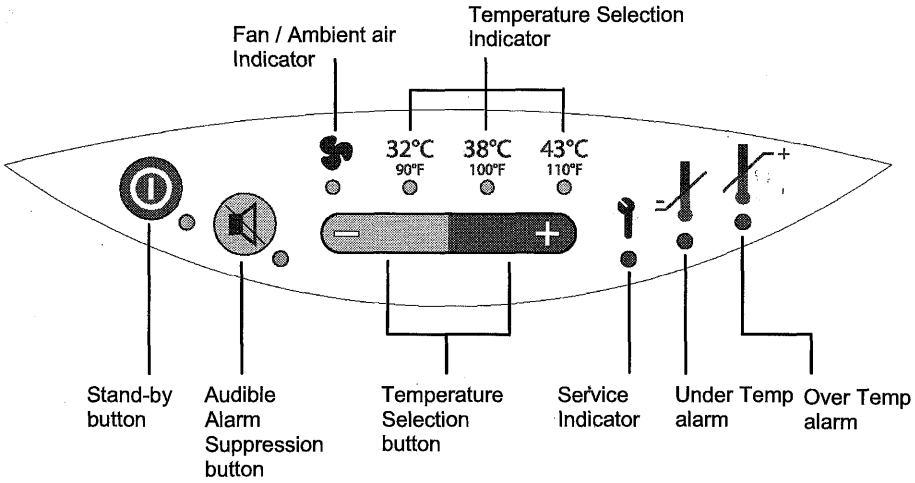
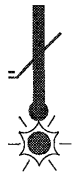
3.2 The Control Panel

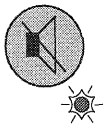
The control panel is located at the front top of the unit and can be controlled by pressure sensitive buttons.
The Mistral-Air® Plus warming unit is very easy to use. All settings are visible on the control panel and you can select the preferred temperature by pressing the Temperature Selection button.
In emergencies, an audible alarm will be activated and an L.E.D. will flash or glow solid red.



Explanation of temperature alarm indications:

	Alarm: An audible alarm is activated and the L.E.D. flashes or glows red. - The primary alarm gives a flashing red L.E.D. - The secondary alarm gives a solid red L.E.D. Cause: There is an over temperature.
	Alarm: An audible alarm is activated and the L.E.D. flashes red. Cause: There is an under temperature.

3.2.1 Extra Options

	Alarm: The L.E.D. is solid red. Cause: The Mistral-Air® Plus warming unit has been used for ≥ 500 hours and routine maintenance is required.
	The audible alarm can be suppressed for 3 minutes by pressing the button. Audible alarm suppression is indicated by a solid orange L.E.D. After 3 minutes, the audible alarm will be activated again.

3.3 The Blankets

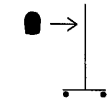
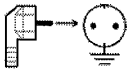
Do not use the Mistral-Air® Plus warming unit with any forced air disposables other than Mistral-Air® blankets. Thermal Injury may result.

Mistral-Air® blankets come in a variety of designs and sizes to meet the customers' needs for preventing and treating hypothermia.

All Mistral-Air® blankets are:
- Latex free
- Made from non-woven polypropylene or polyethylene
- Manufactured to meet flammability standards
- MR Conditional
- Not obstructing x-ray
- Non-conductive
- Non-sterile, except for several dedicated blankets (ask your distributor)
- Packed including an insert in the main languages
- Single-patient use only
- Made from lightweight, soft materials that have been approved for skin contact

	Mistral-Air® blankets need to be used with the soft blue material towards the patient's skin and the white or reflective layer away from the patient's skin. The blue side provides the air distribution towards the patient.
	Never fold the blankets during use
	Thermal injury may occur if heat is applied to ischemic limbs.

4 Preparing the Mistral-Air® Plus warming unit for use

	Before using the Mistral-Air® Plus warming unit, it should be attached to a stand or placed on a table.
	Prior to use, the user needs to check that the Mistral-Air® Plus warming unit, the power cord and the hose are undamaged. In the event of damage do not use the Mistral-Air® Plus warming unit.
	Plug the Mistral-Air® Plus warming unit into an earthed socket.

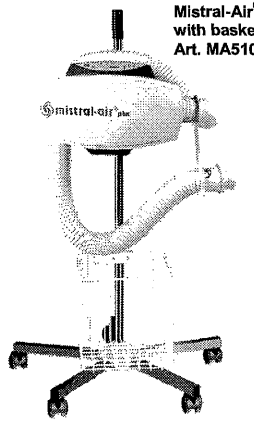
If required, a safety test in accordance with the hospital protocol will follow.

5 Mounting the Mistral-Air® Plus warming unit

The Mistral-Air® Plus warming unit must be mounted securely before use.

The Mistral-Air® Plus warming unit can be mounted onto the Mistral-Air® pole with basket (art. MA5100-B).
The unit should be clamped onto the pole with the top of the clamp less than 80 cm above the floor to prevent tipping over.
Avoid blocking the air inlet (bottom of unit)

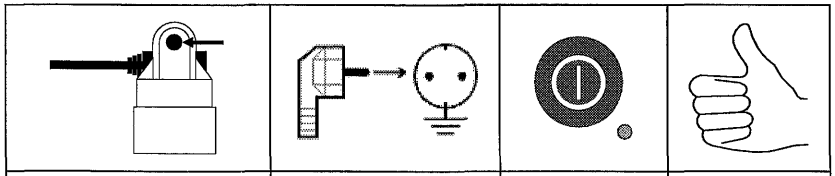
It is also possible to place the Mistral-Air® Plus warming unit on a table. Do not place the unit *in* the bed with the patient.



6 User Instructions

When using the Mistral-Air® Plus warming unit, the instructions below may be useful.

6.1 Connection to Power Supply

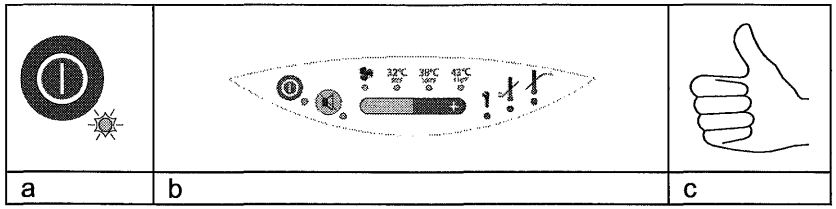


a	b	c	d

a. Make sure the power cord is secured by the cord anchor.
b. Plug the unit into an earthed socket.
c. The unit automatically switches to Stand-by mode, which is indicated by the orange Stand-by L.E.D.
d. The Mistral-Air® Plus warming unit is now in Stand-by mode.

⚠	To remove all power from the Mistral-Air® Plus warming unit, the mains power cord must be removed from the electrical receptacle.

6.2 Activate the Unit

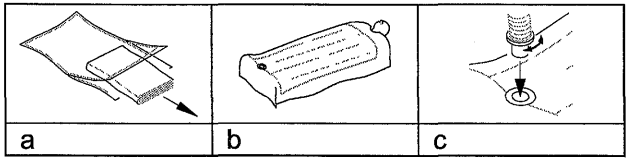


a	b	c

a. Activate the Mistral-Air® Plus warming unit by pressing the Stand-by button.
b. The Mistral-Air® Plus warming unit will now perform a self-test, which includes a flash of all the L.E.D's and a short audible alarm.
c. The Mistral-Air® Plus warming unit will start blowing air at the default temperature setting of 38 °C.

⚠		Do not use the Mistral-Air® Plus warming unit without a Mistral-Air® blanket connected to it. Thermal Injury may result.

6.3 Connecting the Blanket



a	b	c

a. Take the blanket out of the (sterile) package and place it on the patient.
b. Unfold the blanket over the patient.
c. Insert the end of the flexible hose into the air inlet port of the Mistral-Air® blanket. Make sure the hose is fully pushed in.

Detailed instructions are mentioned on the inserts delivered with the Mistral-Air® blankets.

6.4 Warming up with the Mistral-Air® Plus warming unit

6.4.1 Temperature settings

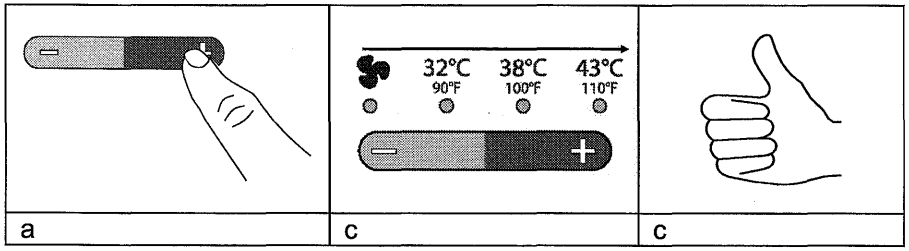
The four settings are:

- Fan - Ambient air
- 32 °C - Low temperature
- 38 °C - Medium temperature
- 43 °C - High temperature

6.4.2 Temperature Selection

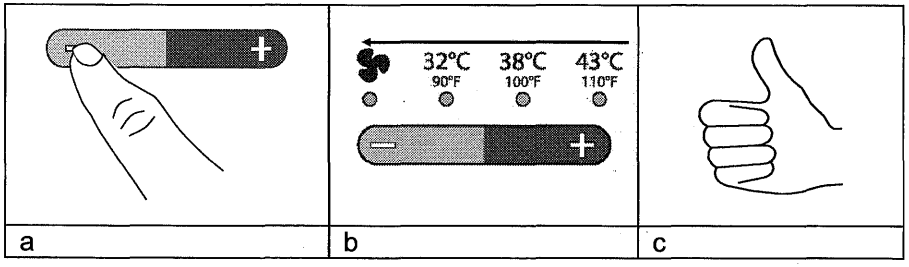
The Mistral-Air® Plus warming unit will start up with the default temperature setting of 38 °C.
By pressing the "–" button twice, the Mistral-Air® Plus will activate the unit to draw in room temperature air and deliver it to the patient via the blanket. The heater will not be activated.
The temperature to the patient will depend on ambient conditions and possible heat from the blower motor.
By pressing the "+" of the temperature selection button the Mistral-Air® Plus will activate the heater to deliver the set temperature: 32 °C, 38 °C or 43 °C.

By pressing the "+" of the temperature selecting button, the temperature setting increases. This is indicated by a green L.E.D.:



a	c	c

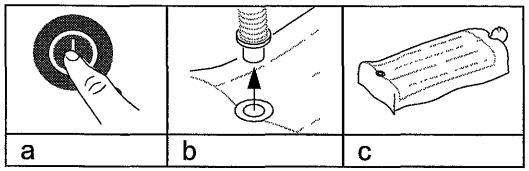
By pressing the "-" of the Temperature Selecting Button, the temperature setting decreases. This is indicated by a green L.E.D.:



a	b	c

After selecting the desired temperature, the L.E.D. below the Temperature Indicator will flash green. After reaching the set temperature (± 2 °C) the flashing L.E.D. will light up permanently.

6.5 Stop Warming



a	b	c

a. Press the Stand-by button
b. Disconnect the hose from the blanket
c. If desired, leave the blanket on the patient

7 Maintenance

The Mistral-Air® Plus warming unit has no parts that can be maintained by users. Users shall not repair or open the Mistral-Air® Plus warming unit in the event of a malfunction. This can damage the appliance and will invalidate the guarantee. The hospital service department or the local supplier shall service the Mistral-Air® Plus warming unit when the service indicator is activated or at least once a year.

Have the Mistral-Air® Plus warming unit serial number ready when you contact the hospital service department or the local supplier for technical support. The serial number is located on the bottom of the unit.

8 Storage and Cleaning

Store the Mistral-Air® Plus warming unit and accessories in a cool and dry place when not in use.
Clean the unit by wiping the outer surface (including the hose) with a soft cloth lightly dampened with a solution of water and mild detergent or a non-staining hospital disinfectant.
Wipe all excess detergent or disinfectant from the unit and allow to air dry.
Do not use alcohol or acid base cleaner on the control panel.
Disconnect from power when cleaning the Mistral-Air® Plus warming unit.
Do not use dripping wet cloths and do not allow water to seep into electrical areas of the Mistral-Air® Plus warming unit.

9 Warnings, Precautions and Symbols

Your Mistral-Air® Plus warming unit was designed and built with safety in mind. The unit should provide reliable service and high quality patient care. However, there is no replacement for care providers being attentive to their patients' needs and equipment operation. Read and understand all warnings and precautions before using / prescribing the Mistral-Air® Plus warming unit

10 Contra-indications

Do not apply heat directly to open wounds. All patients' wounds shall be covered while using the warming system. Do not apply the warming system to ischemic limbs. Use caution and consider discontinuing use on patients during vascular surgery when an artery is clamped to an extremity (i.e. aortic cross-clamping). Use caution and monitor closely if used on patients with severe peripheral vascular disease.

11 Safety precautions

Grounding reliability can be achieved only when the warming unit is connected to a suitable power outlet.

Prevent the blanket material from coming into contact with a laser or an electrosurgical active electrode; rapid combustion could result.

Using other power cords or replacement of parts for internal components than specified by TSCI may result in increased emission or decreased immunity of the Mistral-Air® Plus Warming Unit.

When replacing the hose, do not touch the temperature sensors. If these sensors are touched in any way, the unit must be calibrated.

Portable and mobile RF communication equipment can affect the correct functioning of the Mistral-Air® Plus warming unit.

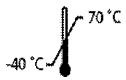
The Mistral-Air® Plus warming unit is not suitable for use during magnetic resonance imaging (MRI) scanning. The warming system may affect the MRI image.

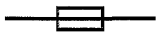
The Mistral-Air® Plus warming unit is fitted with an air filter; however airborne contamination shall be taken into consideration when using the warming system.

12 Symbols

IP21	• Protected against solid foreign objects of 12.5mm Ø and greater. • Protected against vertically falling water drops (according to IEC 60529)
Rx only	Federal US law restricts this device to sale by or on order of a physician (MA1100-US only)
CLASSIFIED c UL us	With respect to electric shock, fire and mechanical hazards only. In accordance with UL 60601-1/CAN/CSA C22.2 No. 601.1 (MA1100-US only)

	Prior to use, the user needs to check that the Mistral-Air® Plus warming unit (including the power cord and the hose) is undamaged. In the event of damage do not use the Mistral-Air® Plus warming unit.
	Connect the Mistral-Air® Plus Warming Unit to an earthed socket only. Risk of electrical shock exists if the equipment is not connected to a properly grounded receptacle.
	No Free Hosing: do not warm a patient without a Mistral-Air® blanket connected to the unit.
	Do not use the Mistral-Air® blankets when damaged.
	Use forced air warming on monitored patients only. Check patient's temperature and skin condition at least every 15 minutes.
	Do not apply to patients with ischemic limbs.
	Do not leave the patient unmonitored during forced air warming. Reduce temperature or discontinue therapy when therapeutic goal is reached or if vital signs instability occurs.
	Avoid blocking the air inlet at the bottom.
	Do not use Mistral-Air® Plus warming unit and blankets near flammable anaesthetics, to avoid the risk of explosion.
	Maintenance and repairs shall be performed by qualified medical instrument technicians only.
	To keep the Mistral-Air® Plus warming unit stable, the wheelbase of the stand must be in a particular ratio to the clamp height. See paragraph 5 ".
	Dispose in accordance with Directive 2002/96/EC (WEEE)
	Do not immerse the Mistral-Air® Plus warming unit in fluid. Clean the appliance with standard cleaning agents. See paragraph 8.

	The Mistral-Air® Plus warming unit is certified according to IEC 60601-1-2 for electromagnetic interference. However, if nevertheless interference effects with different devices occur, the user is encouraged to correct the interference by one or more of the following measures: • Turn devices in the vicinity off and on to isolate the offending device. • Reorient or relocate the other receiving device. • Increase the distance between the interfering device and the Mistral-Air® Plus warming unit, use another power socket. • If assistance is required, contact your local dealer. Using other power cords or replacement of parts for internal components than specified by TSCI may result in increased emission or decreased immunity of the unit • The Mistral-Air® plus warming unit shall not be used adjacent to or stacked with other equipment.
	Do not use dermal medication on the skin surface where forced air warming is used.
	Do not use the Mistral-Air® Plus warming unit with any forced air disposables other than Mistral-Air® blankets. Thermal Injury may result.
	CE marking of conformity 0344 = identification number of KEMA Quality (Notified Body) (MA1100-EU only)
	Serial number
	Article number
	Sterile, method of sterilisation ethylene oxide
	Lot number
	Manufacturer
	Transport and storage ambient temperature range
	Transport and storage relative humidity range

	Attention, see the Instructions for Use
	AC voltage
	Electrical shock hazard. Do not disassemble the Mistral-Air® Plus Warming Unit unless you are a qualified service technician. There are electrically live parts within the unit when it is connected to a power supply.
	Type BF equipment (according to IEC 60601-1)
	Equipotentiality
	Expiry date, year/month
	For single patient use only. Do not re-use.
	Latex-free
	Transformer fuses (250V 800 mA Fast Acting)

13 Warranty

TSCI ('the manufacturer') guarantees end-users that, for a period of 3 years from date of dispatch, every Mistral-Air® Plus warming unit will be free of material and finishing defects with normal use and maintenance.

The guarantee does not apply to any item that is not produced or approved by the manufacturer, if this item is the cause of the malfunction.
The manufacturer has no obligation under this guarantee to perform repairs or replacements resulting partially or in full from accidents, errors, or negligence on the part of the user.

This guarantee applies only to the use of the Mistral-Air® Plus warming unit in combination with the Mistral-Air® blankets. The use of the Mistral-Air® Plus warming unit in combination with blankets from other manufacturers is only allowed if the blanket manufacturer has proven that such a combination is safe.
If this guarantee is utilised, the relevant part shall be returned, properly packed, to the local supplier.

14 Specifications

Article number	MA1100-EU	MA1100-US	MA1100-JP
GMDN-code and term	P 36954 (Heating pad control unit, air) P 36931 (Heating pad, air)		
Dimensions	27.6 cm x 38.5 cm x 23.9 cm (l x w x h)		
Weight	± 6.0 kg		
Hose length	1.8 m		
Power cord length	4.0 m		
Filtration	HEPA, 0.3 µm, 99.99%, H13 conform EN 1822		
Voltage	220-240V~	110-120V~	100-110V~
Frequency	50/60Hz	60HZ	50/60HZ
Current	3A	6A	8A
Peak power	950 W	925 W	1000 W
Average power	525 W	550 W	625 W
Fuses	6.3AT/250V~	10AT/125V~/ 250V~	12.5AT/125V~/ 250V~
Current leakage	< 50 microamperes		
Classification 93/42/EEC & 2007/47/EC	Class IIb		
Classification IEC 60601-1	Class I, Body Floating (BF)		
Classification IEC 60529	IP21		
Ground resistance	< 0.2 ohm		
Set point temperature	32°C, 38°C or 43°C		
Accuracy of temperature	± 2°C		
Low temperature limit	6 °C below set point		
Primary high temperature Limit	≥ 46.5 °C		
Secondary high temperature Limit	(T primary + 2) – 56.4 °C		
Environmental conditions			
Ambient temperature	10°C to 40°C		
Relative humidity	30 % to 75 %		
Atmospheric pressure	70 kPa to 106 kPa		
Transport and storage conditions			
Ambient temperature	- 40°C to 70°C		
Relative humidity	10 % to 90 % (non condensing)		
Atmospheric pressure	50 kPa to 106 kPa		

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